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LEADERSHIP SELECTION IN THE ENTERPRISE OF MEDICAL COUNTERMEASURE DEVELOPMENT

BY

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The threat of domestic terrorism from a chemical, biological, radiological, or nuclear attack is a constant risk that must be managed effectively by those entrusted to protect and prepare our nation. Central to our nation's preparedness are the individuals selected to lead the enterprise of medical countermeasure development. Leaders selected to this post must possess the essential background, skills and experience necessary to achieve success. Equally important, these leaders must be retained in their roles for sufficient time to enact the strategy given to them. Within the U.S. Department of Health and Human Services, the Office of the Assistant Secretary for Preparedness and Response was established with a mission that includes managing the advanced research and development of medical countermeasures through its office of the Biomedical Advanced Research and Development Authority. The U.S. Army Medical Research and Materiel Command manages a similar mission of medical countermeasure development in diverse research laboratories for the Department of Defense. This paper examines the inherent difficulties of managing the unique long-term medical countermeasure programs of the U.S. government by short-term appointed directors in the offices of the ASPR and MRMC.

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LEADERSHIP SELECTION IN THE ENTERPRISE OF MEDICAL COUNTERMEASURE DEVELOPMENT

> "Our national security strategy is, therefore, focused on renewing American leadership so that we can more effectively advance our interests in the 21st century."
>
> —President Barack Obama[1]

President Obama astutely recognized leadership as a key component necessary for an effective national security strategy. Regardless of the dollar figure authorized for a particular national security project, if the requisite leadership is not in place long enough to carry viable projects and ideas through to fruition, then much time, effort, and money is potentially wasted that can leave our nation vulnerable and unprepared. Consequently, selecting and retaining individuals with the required skills, experience and aptitude necessary to serve in roles of senior leadership long enough to achieve program objectives designed to protect our nation is vital if our strategic plans are to be effective and successful. A key example of this concept resides in an essential piece of our national security strategy related to the process of medical countermeasure (MCM) development that is managed by agencies within the U.S. Department of Health and Human Services (DHHS) and the Department of Defense. The inherent difficulties that exist in the management of long-term MCM programs by short-term appointed directors in the offices of the Assistant Secretary for Preparedness and Response and the U.S. Army Medical Research and Materiel Command support consideration of several observations made in this paper on the selection process for these leaders. Subsequent recommendations for improvement of the process could enhance and strengthen overall management of the MCM development enterprise.

Organizational Background

The office of the Assistant Secretary for Preparedness and Response (ASPR) was established in December 2006 as a staff division within DHHS with a mission to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters.[2] As part of this mission, the ASPR serves as the Secretary's principal adviser on matters related to bioterrorism and manages the advanced research and development of MCMs through the subordinate office of the Biomedical Advanced Research and Development Authority (BARDA). Similarly for the Department of Defense, the U.S. Army Medical Research and Materiel Command (MRMC) manages the mission of MCM development for the U.S. Army by providing oversight to the various Army research institutes' chemical and biological defense programs. MRMC capabilities include a unique infrastructure, highly skilled personnel, and dedicated scientific and technical expertise to manage the complex and diverse chemical and biological threats and to provide materiel life-cycle management that protects, treats, and optimizes service member health and performance across the full spectrum of operations.[3]

Leadership Background

The Assistant Secretary for Preparedness and Response is a politically appointed position chosen by the Secretary, DHHS. As a political appointee, the selection is, by definition, based in part on politics and political loyalty. Additionally, the ASPR reports directly to the Secretary, DHHS and is responsible for formulating, promoting, and directing the Department's preparedness and response policies and programs. In this role, the ASPR works with subordinate office directors and staff to

develop new policies, determine new or modified program directions for the agency as problems are identified, and establish priorities and metrics to evaluate success.

The Commander of the U.S. Army Medical Research and Materiel Command is a merit-based selection from a relatively small pool of eligible and promotable, one-star general officers. The dual-hatted Commander of the U.S. Army Medical Command, who also serves as The U.S. Army Surgeon General, gives final approval on the selection based on each eligible officer's qualifications, personality, skills, experiences, and availability. The roles and responsibilities for the MRMC Commander in leading the organization are similar to those mentioned above for the ASPR.

MCM Development Background

MCM development involves the production of vaccines and therapeutics for prophylaxis and treatment of chemical, biological, radiological, and nuclear (CBRN) threats, as well as the creation of supporting diagnostic tools. MCMs are the same type of Food and Drug Administration-approved therapeutics (small molecule drugs and biologics), vaccines, and medical devices developed by the pharmaceutical and medical device industry for commercial markets. Pharmaceutical medicine is an industry with huge, multi-million to billion dollar, up-front investments that involve 10-20 years of research and development which may or may not result in a marketable drug that provides a return for its investors. A key difference between pharmaceutical industry development of therapeutics and vaccines for commercial markets versus MCM development by the government or military is that specific MCMs have little to no commercial viability (i.e., financial return on investment that can justify their being pursued) due to the nature of the indication they are designed and developed to

address (CBRN countermeasures). Because CBRN attacks are low probability–high consequence events, there is not a sustained market demand to justify commercial investment in the majority of MCM projects. As a result, amassing strategic national stockpiles by Federal and State governments are the most likely market for MCMs. The need to fund MCM development is not only vital to our national interests due to the catastrophic medical, societal, and economic outcomes associated with an event for which we were unprepared to respond, but is mandated through federal legislation for the prophylaxis and treatment of the U.S. population in the event of a global public health emergency.[4]

To this end, BARDA was created under ASPR to manage the advanced development and acquisition of medical countermeasures for CBRN threats and emerging infectious diseases for the U.S. civilian population. With this authority, BARDA works with companies to bridge the "valley of death" funding gap that exists between the early stages of product development, that are typically funded by grants and angel investors, and the acquisition of approved or approvable MCMs for the strategic national stockpile.[5] Agencies within the Department of Defense, to include MRMC, work hand-in-hand with agencies within DHHS in MCM development.

Management Challenges of MCM Development

MCM development is a constantly changing business environment requiring mid- and upper-level managers to balance both continuity and change. Changes to regulatory requirements, the national security strategy, or the emergence of new terrorist threats can result in adjustments needed to manage the risk and keep development on track.[6] To do so effectively requires the selection of individuals with an

appreciable understanding of not only the science involved in the research and development process, but also a track record of success in the ability to strategically manage an organization operating in a demanding, complex, political, and highly bureaucratic environment.

Observations and Recommendations

The career development of mid-level managers (from organizations of the size and complexity as the offices of the ASPR or MRMC) is fittingly modeled in corporate industry. Upper-level management of mid- and top-tier companies typically identifies a pool of potential future leaders from mid-level management relatively early in their careers. In fact, succession planning from within the ranks typically begins 5-10 years out and enables a continuity of leadership that has proven to be a trademark of some of the most successful corporations, preserving the core while stimulating progress.[7] These mid-level leaders, who are judged to possess the core strengths necessary to enhance the goals and preserve the strategic culture of the company, are then groomed for their future roles through a variety of rotational assignments and field experiences in order to strengthen and develop their overall knowledge base and expertise. As an example, a typical progression of assignments for up-and-coming individuals may begin with a job in sales, followed later by experience in marketing, then new product development and research, exposure to portfolio management, then emerging markets. To gain global experience, a position with responsibility for a geographic area would give valuable profit and loss exposure. Assignment as General Manager to a foreign country would finally assist with adding breadth, as well as depth, in the grooming toward potential attainment of CEO status.[8]

Applying a leadership preparation framework used in industry by many proven successful and diversified companies to the career development of government or military strategic leaders who have responsibility for MCM development could have multiple benefits. It could enable those prospective leaders within this endeavor who have displayed genuine aptitude for senior leadership roles to be made aware of opportunities for upward mobility in their early careers while simultaneously broadening their situational awareness and understanding of the link between tactical projects, operational programs, and strategic enterprises. Additionally, this approach could serve to strengthen not just the ability to select and promote properly qualified personnel, but would enhance overall management acumen within the organizations of the MCM enterprise. Consequently, a more defined and, perhaps, institutionalized format of job experience should be considered. This concept is supported by a highly successful strategy executive with over 20 years of consulting experience in the commercial life sciences industry who states, “Leadership development does not merely involve the selection of certain individuals who are groomed solely for ascendancy to the top spot in an organization.”[9] Leadership training programs within an organization will never be wasted effort, whether or not the recipients ever make it to lead or command at the strategic level.

Given the importance that MCM development occupies in our national security strategy, several issues surface in an examination of the current selection process for the leaders charged with managing this enterprise. The ASPR and MRMC Commander are typically physicians with a breadth of management experience, but little to no experience related to the technical, regulatory, and economic aspects related to the

research and development process of MCMs. Consequently, the steep learning curve forces new leaders to lean heavily on either career civil service employees or senior military officers who remain from the previous command.[10, 11] However, animosities held against the incoming leader or reluctance by these mid-level civil service managers to align themselves with the direction provided by the new leadership can exacerbate the aforementioned issues, amplify inefficiencies, and lead to ineffective policy decisions that limit or impede progress. Some of these mid-level program managers may choose to "wait out" the political appointees' tenure in hopes that the next administration will have a strategy more in line with advancing their particular product, program, or mindset.[12] Institutionalizing a mid-level career development program of vetted, trusted advisers on various programs to form a leadership transition team could effectively minimize this negative effect on the organization by providing some exposure for these managers to see the bigger picture of strategic vision.

Further issues for consideration concern the length of office tenure for these leaders. The length of service for most political appointees and military commanders averages between 24-36 months, giving them relatively short time to enact program or policy objectives.[13] In contrast, private industry has come to realize that a changeover in leadership at a brand manager level every 2-3 years is extremely destabilizing and disruptive to the product workforce and to their customers.[14] Corporate leaders are taking action to address this issue.

The existing selection processes within the office of the ASPR and MRMC, therefore, provide an average 2-3 year rotation in office of senior leaders who are more likely to represent the strategic thinking of the current political/military administration.

As representatives who are chosen by an elected administration, one could also infer that the new leaders possess and represent the mindset of the majority of the nation as well. Accordingly, the selection processes inject a fresh perspective to address festering problems and vexing issues in a new light due to the breadth of experience and knowledge that is brought to the position by new leadership.[15] However, because of short tenures in office, the high turnover of senior leaders who manage our nation's MCM development enterprise has the potential to cause significant national security lapses. With each turnover, a significant leadership vacuum is created as these now-experienced leaders move on and each incoming leader must scramble to gain the job-specific experience necessary to make informed decisions that is necessary for continued progress.[16]

Coupled with a relatively short tenure, other significant challenges face the incoming ASPR or MRMC Commander. As a political appointee, it is expected that a changeover in political administration will result in an ushering out with the old and in with the new. An incoming leader who is not knowledgeable in the business aspects of MCM development will not easily recognize what projects need to be sustained or what processes may be broken or need improvement. As previously alluded to, uninformed changes can be extremely disruptive and damaging to the enterprise effort. For example, the incoming ASPR may not even have an opportunity to meet with their departing predecessor to perform an adequate transition of the management of programs and, more importantly, to allow passage of the current strategy and organizational vision to effectively enable a smooth transition and continuity of progress.

Depending on the rotation and flexibility of military assignments, the same situation occasionally occurs with incoming military commanders.

Additionally, as a political appointee the ASPR may find that they serve numerous masters. Members of Congress, special interest groups in the form of lobbyists, and the DHHS Secretary have the potential to exert influence that may run counter to the ASPR's independent perspective in making objective decisions or in the way that MCM contracts are awarded. While somewhat more immune or insulated from political control, even senior military officers occasionally feel the pressures that political offices and interest groups can wield.[17]

How does a dedicated, conscientious political appointee or military commander who is charged with managing our nation's MCM program best deal with all of these challenges? First is their commitment to the fact that their selection for the leadership role that they occupy and serve in is a public trust. In no small part, the safety, readiness, and preparedness of the nation and the military to respond to a CBRN attack hinges on their ability to carry out the strategic mission given to them. Their ability to effectively communicate with the internal and external stakeholders with whom they cooperate is pivotal to the success of their mission.[18, 19] Second is the acceptance and communication to their team that because their projected tenure is typically short, they must work with a great sense of urgency to quickly identify the few key issues with major impact that they can most influence and complete. Lastly, they must continue to demonstrate the utmost commitment to work selflessly, tirelessly, and diligently to make incremental improvements and significant forward progress on long-term projects that will place their successor closer to achieving the administration's desired strategic

outcome.[20] Very possibly, these character traits are what led to their selection to the senior leadership roles in which they serve.

In review, if career civil service scientists and managers are to provide the continuity between one administration and the next, it is important that significant effort be directed at selecting, training, and providing incentives to the appropriate mid-level managers in previously discussed leadership principles. Knowing "the business" and knowing "management" are two key skills that must be developed at all levels. Leadership development, though, involves more than simply enabling one to add to their list of knowledge, skills, and abilities on a résumé. A more desirable focus of any leadership development practice is an orientation toward *future* leadership competencies that drive the development of desired behaviors and values. An insightful observation further explained by a strategy consultant in the life sciences industry, "the greater challenge – one with more potential impact – involves instilling a true leadership mindset or discipline into the middle management of a company from the top down. It involves identifying and motivating individuals to think beyond their given task or role within the company – in effect, to think beyond themselves – in a selfless effort to move organizational objectives forward. Leadership discipline involves upper-level management promoting desirable individual traits that are necessary to maintain the core strength of the company and pushing those traits down into the organization. Incentives, rewards, and career paths need to be rethought to reflect this core strengthening of the organization."[21]

In determining who should be invested in with leadership training, a 2001 examination of the best practices of leadership development currently in use by industry

found that leadership potential was found at all levels, not merely in top management. Educating reluctant individuals on their role in the leadership process will better prepare and potentially enable them to participate in future leadership roles.[22] The military has a long tradition and history of maintaining an excellent system for professional military development and growth of all ranks that is well laid out and programmatic…a virtual "leadership machine."[23] Such training needs to continue to be updated and developed in all levels of civilian and military professional advancement. Professional military development of officers, non-commissioned officers, and enlisted soldiers demonstrates this concept well through mandatory developmental leadership and training courses that are required for earning skill badges, certain awards and medals, honorary distinctions, and competitive selection in promotional advancements. In fact, in an examination of leadership development in industry it was identified that among leading-edge companies the true measure of success was the value placed on its people, not its property. True success for these companies is defined by building and retaining their investment in the "intellectual capital" that the employees possess.[24] This sort of approach could be included in the education of potential future leaders of the Office of the ASPR and MRMC who have limited experience in the enterprise of MCM research and development.

A final point of observation in regards to maintenance of program continuity is that a logical, overlapping handover period for incoming and outgoing directors should be established and institutionalized to ensure a proper transfer of ongoing issues, unfinished projects, and beneficial knowledge that would ease the leadership transfer, maximize and aid strategic continuity, and minimize transition-associated risks. Longer

tenures of perhaps 4-6 years should also be evaluated for long-term directors of MCM development programs as a means to avoid the hazards that frequent turnover presents, provided that annual performance evaluations and positive command climate or employee morale support such a decision. The improved stability and consistency in the leadership and management of such a vital mission as MCM development presents a strong argument for this consideration. One must realize and understand, though, that leadership development is a process, not an event. Leadership development must be consistently applied as an investment in the future that may take years before dividends are realized.[25]

Endnotes

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[11] MG James Gilman, Commander, U.S. Army Medical Research and Materiel Command, interview by the author, Ft. Detrick, MD, November 19, 2010.

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[24] Day, Halpin, “Leadership Development: A Review of Industry Best Practices”, 9-10.

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